

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
2685.1003-001

APPLICATION NO.  
09/383,054

FOURTH SUPPLEMENTAL  
INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

APPLICANT  
David A. Edwards, *et al.*

FILING DATE  
August 25, 1999

CONFIRMATION NO.  
6042

GROUP  
1615-1616

April 1, 2003

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
*	AJ3	2,470,296	05/17/49	Fields
	AK3	2,533,065	12/05/50	Taplin <i>et al.</i>
	AA4	2,992,645	07/18/61	Fowler
	AB4	3,781,230	12/25/73	Vassiliades <i>et al.</i>
	AC4	3,957,965	05/18/76	Harley <i>et al.</i>
	AD4	4,009,280	02/22/77	Macarthur, <i>et al.</i>
	AE4	4,089,800	05/16/78	Temple
	AF4	4,161,516	07/17/79	Bell
	AG4	4,173,488	11/06/79	Vassiliades, <i>et al.</i>
	AH4	4,272,398	06/09/81	Jaffe
	AI4	4,352,883	10/05/82	Lim
	AJ4	4,391,909	07/05/83	Lim
	AK4	4,466,442	08/21/84	Hilman, <i>et al.</i>
	AA5	4,480,041	10/30/84	Myles, <i>et al.</i>
	AB5	4,524,769	06/25/85	Wetterlin
	AC5	4,572,203	02/25/86	Feinstein
	AD5	4,590,206	05/20/86	Forrester <i>et al.</i>
	AE5	4,615,697	10/07/86	Robinson
	AF5	4,679,555	07/14/87	Sackner
	AG5	4,741,872	05/03/88	De Luca, <i>et al.</i>
	AH5	4,743,545	05/10/88	Torobin
	AI5	4,774,958	10/04/88	Feinstein
	AJ5	4,789,550	12/06/88	Hommel, <i>et al.</i>
	AK5	4,818,542	04/04/89	De Luca, <i>et al.</i>
SR	AA6	4,847,091	07/11/89	Illum

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054	
<p>FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>APR 09 2003</p> <p>April 1, 2003</p> <p>(Use several sheets if necessary)</p>		APPLICANT David A. Edwards, <i>et al.</i>		
		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUP 1615-16/6

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
JL	AB6	4,855,144	08/08/89	Leong, <i>et al.</i>
	AC6	4,857,311	08/15/89	Domb, <i>et al.</i>
	AD6	4,861,627	08/29/89	Mathiowitz, <i>et al.</i>
	AE6	4,865,789	09/12/89	Castro, <i>et al.</i>
	AF6	4,904,479	02/27/90	Illum
	AG6	4,917,119	04/17/90	Potter, <i>et al.</i>
	AH6	4,963,297	10/16/90	Madden
	AI6	4,976,968	12/11/90	Steiner
	AJ6	4,994,281	02/19/91	Muranishi, <i>et al.</i>
	AK6	5,033,463	07/23/91	Cocozza
	AA7	5,064,650	11/12/91	Lew
	AB7	5,069,936	12/03/91	Yen
	AC7	5,075,109	12/24/91	Tice <i>et al.</i>
	AD7	5,100,669	03/31/92	Hyon <i>et al.</i>
	AE7	5,123,414	06/23/92	Unger
	AF7	5,145,684	09/08/92	Liversidge <i>et al.</i>
	AG7	5,160,745	11/03/92	De Luca <i>et al.</i>
	AH7	5,169,871	12/08/92	Hughes <i>et al.</i>
	AI7	5,174,988	12/29/92	Mautone <i>et al.</i>
	AJ7	5,195,520	03/23/93	Schlieff, <i>et al.</i>
	AK7	5,204,108	04/20/93	Illum
	AA8	5,204,113	04/20/93	Hartley, <i>et al.</i>
	AB8	5,260,306	11/09/93	Boardman <i>et al.</i>
	AC8	5,271,961	12/21/93	Mathiowitz, <i>et al.</i>
JL	AD8	5,306,483	04/26/94	Mautone

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(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
JK	AE8	5,327,883	07/12/94	Williams, <i>et al.</i>
	AF8	5,334,381	08/02/94	Unger
	AG8	5,340,587	08/23/94	Milhalko <i>et al.</i>
	AH8	5,352,435	10/04/94	Unger
	AI8	5,384,133	01/24/95	Boyes <i>et al.</i>
	AJ8	5,393,524	02/28/95	Quay
	AK8	5,407,609	04/18/95	Tice, <i>et al.</i>
	AA9	5,456,917	10/10/95	Wise <i>et al.</i>
	AB9	5,466,841	11/14/98	Horrobin, <i>et al.</i>
	AC9	5,482,946	01/09/96	Clark, <i>et al.</i>
	AD9	5,518,709	05/21/96	Sutton, <i>et al.</i>
	AE9	5,518,998	05/21/96	Bäckström, <i>et al.</i>
	AF9	5,551,489	09/03/96	Trofast, <i>et al.</i>
	AG9	5,580,575	12/03/96	Unger <i>et al.</i>
	AH9	5,607,695	03/04/97	Ek <i>et al.</i>
	AI9	5,607,915	03/04/97	Patton
	AJ9	5,612,053	03/18/97	Baichwal <i>et al.</i>
	AK9	5,614,216	03/25/97	Janoff
	AA10	5,654,007	08/05/97	Johnson
	AB10	5,690,954	11/25/97	Illum
	AC10	5,698,721	12/16/97	Heath
	AD10	5,707,644	01/13/98	Illum
	AE10	5,709,884	01/20/98	Trofast, <i>et al.</i>
	AF10	5,780,014	07/14/98	Eljamal
JK	AG10	5,795,594	08/18/98	York, <i>et al.</i>

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6/11/2004

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		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUP 1615/616

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
✓	AH10	5,804,212	09/08/98	Illum
	AH10	5,814,607	09/29/98	Patton
	AJ10	5,830,853	11/03/98	Bäckström, <i>et al.</i>
	AK10	5,851,453	12/22/98	Hanna, <i>et al.</i>
	AA11	5,874,063	02/23/99	Briggner <i>et al.</i>
	AB11	5,885,613	03/23/99	Holland <i>et al.</i>
	AC11	5,902,802	05/11/99	Heath
	AD11	5,922,354	07/13/99	Johnson
	AE11	5,928,469	07/27/99	Franks <i>et al.</i>
	AF11	5,993,783	11/30/99	Eljamal
	AG11	6,019,968	02/01/00	Platz
	AH11	6,051,256	04/18/00	Platz
	AI11	6,063,138	05/16/00	Hanna <i>et al.</i>
	AJ11	6,080,721	06/27/00	Patton
	AK11	6,103,270	08/15/00	Johnson
	AA12	6,123,936	09/26/00	Platz
	AB12	6,136,346	10/24/00	Eljamal
	AC12	6,153,224	11/28/02	Staniforth
	AD12	6,187,330 B1	02/13/01	Wang <i>et al.</i>
	AE12	6,187,344 B1	02/13/01	Eljamal
	AF12	6,231,851 B1	05/15/01	Platz
	AG12	6,258,341 B1	07/10/01	Foster
	AH12	6,303,582 B1	10/16/01	Eljamal
	AI12	6,309,671 B1	10/30/01	Foster
✓	AJ12	6,315,983 B1	11/13/01	Eistetter

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EXAMINER <i>John Choi</i>	DATE CONSIDERED 6/11/2004
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FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	TRANSLATION NO
✓	AQ2	WO 80/02365	13/11/80	PCT				
	AL3	WO 86/06959	04/12/86	PCT				
	AM3	WO 88/04556	30/06/88	PCT				
	AN3	WO 88/09163	01/12/88	PCT				
	AO3	WO 91/04732	18/04/91	PCT				
	AP3	WO 91/06286	16/05/91	PCT				
	AQ3	WO 91/06287	16/05/91	PCT				
✓	AL4	WO 91/12823	05/09/91	PCT				
	AM4	This reference number intentionally left blank						
✓	AN4	WO 92/18164	29/10/92	PCT				
	AO4	WO 92/21382	10/12/92	PCT				
	AP4	WO 93/25221	23/12/93	PCT				
	AQ4	WO 94/04133	03/03/94	PCT				
	AL5	WO 94/07514	14/04/94	PCT				
	AM5	WO 94/08627	28/04/94	PCT				
	AN5	WO 94/16739	04/08/94	PCT				
	AO5	WO 95/00127	05/01/95	PCT				
	AP5	WO 95/07072	16/03/95	PCT				
	AQ5	WO 95/24183	14/09/95	PCT				
	AL6	WO 95/31479	23/11/95	PCT (Platz)				
	AM6	WO 95/35097	28/12/95	PCT				
✓	AN6	WO 96/09814	04/04/96	PCT				
	AO6	This reference number intentionally left blank						
✓	AP6	WO 96/23485	08/08/96	PCT				

EXAMINER John Chen	DATE CONSIDERED 6/11/2004
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				GROUP 1615/616	

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO	
✓	AQ6	WO 96/32096	17/10/96	PCT (Eljamal)				
	AL7	WO 96/32116	17/10/96	PCT (Eljamal)				
	AM7	WO 96/32149	17/10/96	PCT (Platz)				
	AN7	WO 96/40963	19/12/96	PCT				
	AO7	WO 96/41873	27/12/96	PCT				
	AP7	WO 97/03649	06/02/97	PCT				
✓	AQ7	WO 97/36574	09/10/97	PCT				
	AL8	This reference number intentionally left blank						
✗	AM8	WO 98/16205	23/04/98	PCT (Foster)				
	AN8	WO 98/29096	09/07/98	PCT (Gordon)				
	AO8	WO 98/29098	09/07/98	PCT (Gordon)				
	AP8	WO 98/29140	09/07/98	PCT (Gordon)				
	AQ8	WO 98/29141	09/07/98	PCT (Gordon)				
	AL9	WO 98/51278	19/11/98	PCT				
	AM9	WO 99/16419	08/04/99	PCT				
	AN9	WO 99/16420	08/04/99	PCT				
	AO9	WO 99/16421	08/04/99	PCT				
	AP9	WO 99/16422	08/04/99	PCT				
	AQ9	WO 99/66903	29/12/99	PCT				
	AL10	WO 00/15262	23/03/00	PCT (Clark)				
	AM10	WO 00/21594	20/04/00	PCT (Clark)				
	AN10	WO 00/33811	15/06/00	PCT				
	AO10	WO 01/00312 A1	04/01/01	PCT (Bennett)				
✓	API0	WO 01/13891 A3	01/03/01	PCT				

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AQ10	WO 01/32144 A1	10/05/01	PCT (Lechuga-Ballesteros)			
	AL11	WO 02/09669 A3	07/02/00	PCT (Snyder)			
	AM11	WO 02/11695 A3	14/02/02	PCT (Stevenson)			
	AN11	WO 02/054868 A2	18/07/02	PCT (Weickert)			
	AO11	WO 02/055101 A2	18/07/02	PCT (Hastedt)			
	AP11	WO 02/087542 A1	07/11/02	PCT (Bot)			
	AQ11	EP 0 072 046 A1	16/02/03	EPO			
	AL12	EP 0 213 303 B1	04/09/91	EPO			
	AM12	EP 0 257 915 A1	02/03/88	EPO			
	AN12	EP 0 257 956 B1	20/05/92	EPO			
	AO12	EP 0 324 938 A1	26/07/89	EPO			
	AP12	EP 0 335 133 A2	04/10/89	EPO			
	AQ12	EP 0 458 745 A1	14/05/91	EPO			
	AL13	EP 0 510 731 A1	28/10/92	EPO			
	AM13	EP 0 634 166 A1	18/01/95	EPO			
	AN13	EP 0 656 206 A1	07/06/95	EPO			
	AO13	1 288 583	17/11/69	GB			
	AP13	1,300,009	05/05/92	Canada			
	AQ13	1,302,258	02/06/92	Canada			
	AL14	2,058,428	05/09/00	Canada			
	AM14	2,085,884	30/12/91	Canada			
	AN13	2,111,002	22/08/00	Canada			
	AO14	2,126,244	26/09/00	Canada			
	AP14	2,166,108	05/01/95	Canada			
	AQ14	2,170,394	02/03/95	Canada			

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

ARS	Adjei, A., and Garren, J., "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <i>Pharm. Res.</i> , 7(6):565-569 (1990).
AS5	Allen, T.M., <i>et al.</i> , "Subcutaneous Administration of Liposomes: A Comparison with the Intravenous and Intraperitoneal Routes of Injection," <i>Biochem. et Biophys. Acta.</i> 1150:9-16 (1993).
AT5	Altshuler, B., <i>et al.</i> , "Aerosol Deposition in the Human Respiratory Tract," <i>Am. Med. Assoc. Arch. of Indust. Health</i> 15:293-303 (1957).
AU5	Anderson, P.J., <i>et al.</i> , "Effect of Cystic Fibrosis on Inhaled Aerosol Boluses," <i>Am. Rev. Respir. Dis.</i> , 140:1317-1324 (1989).
AV5	Anderson, M., <i>et al.</i> , "Human Deposition and Clearance of 6- $\mu$ m Particles Inhaled with an Extremely Low Flow Rate," <i>Exp. Lung Res.</i> , 21:187-195 (1995).
AW5	Barrera, D.A., <i>et al.</i> , "Synthesis and RGD Peptide Modification of a New Biodegradable Copolymer: Poly(lactic acid-co-lysine)," <i>J. Am. Chem. Soc.</i> , 115:11010-11011 (1993).
AX5	Beck, L.R., <i>et al.</i> , "A New Long-Acting Injectable Microcapsule System for the Administration of Progesterone," <i>Fertility and Sterility</i> , 31(5):545-551 (1979).
AY5	Benita, S., <i>et al.</i> , "Characterization of Drug-loaded Poly( <i>d,l</i> -lactide) Microspheres," <i>J. of Pharm. Sci</i> 73(12):1721-1724 (1984).
AZ5	Blackett, P.M., and G. Buckton, "A Microcalorimetric Investigation of the Interaction of Surfactants with Crystalline and Partially Crystalline Salbutamol Sulphate in a Model Inhalation Aerosol System," <i>Pharmaceutical Research</i> , 12(11):1689-1693 (1995).
AR6	Brain, J.D., "Physiology and Pathophysiology of Pulmonary Macrophages". In <i>The Reticuloendothelial System</i> , Reichard and Filkins, eds. (Plenum Press, New York), pp. 315-327 (1985).
AS6	Brown, A.R., <i>et al.</i> , "Propellant-Driven Aerosols of Functional Proteins as Potential Therapeutic Agents in the Respiratory Tract," <i>Immunopharmacology</i> , 28:241-257 (1994).
AT6	Byron, P.R., "Determinants of Drug and Polypeptide Bioavailability from Aerosols Delivered to the Lung," <i>Adv. Drug. Del. Rev.</i> , 5:107-132 (1990).
AU6	Carroll, B.A., <i>et al.</i> , "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents," <i>Investigative Radiology</i> , 15:260-266 (1980).

EXAMINER

DATE CONSIDERED

*John Choi*

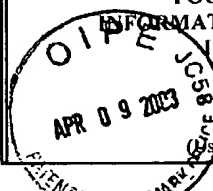
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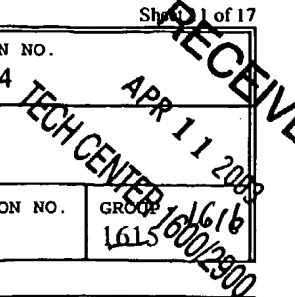
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AV6	Carroll, B.A., <i>et al.</i> , "Ultrasonic Contrast Enhancement of Tissue by Encapsulated Microbubbles," <i>Radiology</i> , 143:747-750 (1982).	
AW6	Ch'ng, H.S., <i>et al.</i> , "Bioadhesive Polymers as Platforms for Oral Controlled Drug Delivery II: Synthesis and Evaluation of Some Swelling, Water-Insoluble Bioadhesive Polymers," <i>J. of Pharm Sci.</i> , 74(4):399-405 (1985).	
AX6	Clark, A., and P. Byron, "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank. Atm.org.</i> , 166:13-24 (1986).	
AY6	Clark, A.R., and M. Egan, "Modeling the Deposition of Inhaled Powdered Drug Aerosols," <i>J. Aerosol Sci.</i> , 25(1):175-186 (1994).	
AZ6	Clay, M.M., <i>et al.</i> "Effect of Aerosol Particle Size on Bronchodilatation with Nebulised Terbutaline in Asthmatic Subjects," <i>Thorax</i> 41:364-368(1986).	
AR7	Cohen, S., <i>et al.</i> , "Controlled Delivery Systems for Proteins Based on Poly(Lactic/Glycolic Acid) Microspheres," <i>Pharm. Res.</i> 8(6):713-720(1991).	
AS7	Colthorpe, P., <i>et al.</i> , "The Pharmacokinetics of Pulmonary-Delivered Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," <i>Pharm. Res.</i> 9(6):764-768 (1992).	
AT7	Daly, W.H., <i>et al.</i> , "The Preparation of N-Carboxyanhydrides of $\alpha$ -Amino Acids Using Bis(Trichloromethyl) Carbonate," <i>Tetrahedron Lett.</i> , 29(46):5859-5862 (1988).	
AU7	Damms, B. and W. Bains, "The Cost of Delivering Drugs without Needles," <i>J. Controlled Release</i> , 8-11 (1996).	
AV7	Darquenne, C., and M. Paiva, "Two and Three-Dimensional Simulations of Aerosol Transport and Deposition in Alveolar Zone of Human Lung," <i>Journal of Applied Physiology</i> , 80(4):1401-1414 (1996).	
AW7	Davies, C.N., <i>et al.</i> , "Breathing of Half-micron Aerosols. I. Experimental.," <i>J. of Appl. Physiol.</i> 32(5):591-600(1972).	
AX7	Davis, S.S., and L. Illum, "Polymeric Microspheres as Drug Carriers," <i>Biomaterials</i> , 9:111-115 (1988).	
AY7	Davis, S.S., <i>et al.</i> , "Microspheres as Controlled-Release Systems for Parenteral and Nasal Administration," <i>Controlled Release Technology</i> , Chapter 15, pp. 201-213 (1987).	
AZ7	Dorries, A.M., and Valberg P.A., "Heterogeneity of Phagocytosis for Inhaled Versus Instilled Material," <i>Am. Rev. Respir. Dis.</i> , 146:831-837 (1992).	

EXAMINER <i>John Davis</i>	DATE CONSIDERED 6/1/2004
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		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUPE 1615


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		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUP 1615/616

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		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUP 1615 / 616

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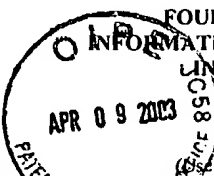
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